# AUDIT REPORT FOR SWITZERLAND JANUARY 25 THROUGH FEBRUARY 7, 2000

#### INTRODUCTION

#### **Background**

This report reflects information that was obtained during an audit of Switzerland's meat inspection system (BVET) from January 25 through February 7, 2000. Five of the five establishments certified to export meat to the United States were audited. One of these was a slaughter establishment; the other four were conducting processing operations.

The last on-site audit of the Swiss inspection system was conducted in January 1999. Five establishments were audited. All were acceptable. The principal concerns with the system at that time were the following:

- 1. Performance standards for *Salmonella* species testing were not established according to U.S. requirements.
- 2. Detection, tolerance and action level for *Listeria monocytogenes* procedures were not comparable to U.S. requirements.
- 3. Monitoring for arsenic and mercury residues was not being done.
- 4. Species identification testing was not being performed.

Product prepared from beef of Switzerland origin is not used for export to U.S. due to bovine *spongiform encephalopathy* (BSE).

During the calendar year 1999, Swiss establishments exported 25,765 pounds of shelf stable cured-dried beef or pork to the United States. One lot of 979 pounds (0.03%) was rejected on port of entry reinspection for sulfa residue violation.

#### **PROTOCOL**

This on-site audit was conducted in four parts. One part involved visits with Swiss national meat inspection officials to discuss oversight programs and practices, including enforcement activities. The second entailed an audit of a selection of records in the meat inspection headquarters facilities preceding the on-site visits. All of the five establishments were selected for on-site audit. The third part was conducted by on-site visits to establishments. The fourth was a visit to two laboratories: one national reference laboratory, which also conducted *Salmonella* species testing, and one BVET contract private laboratory testing for chemical residues and *E. coli*.

Program effectiveness determinations focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures

(SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/ processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) systems and the *Escherichia coli* (*E. coli*) testing program, and (5) enforcement controls, including the testing program for *Salmonella* species.

During all on-site establishment visits, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials

#### RESULTS AND DISCUSSION

## **Summary**

Effective inspection system controls were found to be in place in all establishments audited. However, some of the deficiencies and/or variations observed were:

- HACCP-implementation deficiencies were found in four establishments 121, 205, 215, and 293 for failing to conduct pre-shipment review, in two establishments 205 and 215 for failing to document corrective actions taken, two establishments 215 and 293 for failing to identify critical control points, and three establishments 121, 201 and 215 for failing to analyze or identify all hazards likely to occur.
- Ready-to-eat cure-dried products are routinely sampled by the establishments and tested by accredited private laboratories for *Listeria monocytogenes* and *Salmonella* species according to qualitative enrichment microorganism's method. The procedures, Swiss authorities maintain, ensure detection in 25g of product and 100 cfu/g with a water activity of < 0.92 for *Listeria*, and that the maturation process (cure-drying) inhibits the growth of *Listeria* and *Salmonella* at water activity of < 0.92 and < 0.95 respectively, thus rendering *Enterobacteriaceae* microorganisms virtually harmless. Swiss authorities were of the opinion that the FSIS standard for these products is not applicable and dehydration for over six months registers erroneous results. Swiss authorities expect FSIS to exempt ready-to-eat dehydrated products from being routinely tested.
- Dead on arrival (DOA) carcasses, condemned materials, and contaminated products fallen on floors are not denatured/decharacterized before shipping off-premises. However, these are shipped in tight containers and incinerated in a rendering facility under State Veterinary Inspection Service control. Brains, spinal cords, eyes and tonsils of animals suspected of carrying notifiable diseases, including the BSE-suspect animals, are denatured with a dye at the slaughterhouse, kept under inspection control, and incinerated in a specified rendering facility.

### **Entrance Meeting**

On January 25, a meeting was held at the BVET headquarters in Bern. It was attended by Drs. Peter Dollinger, Head of Division of Permits and Inspection; Dr. Silke Holznagel, Chief Export Permits and Inspections; Dr. Jakob Schluep, Chief of Veterinary Border Control (Imports); Dr. Andreas Flukiger, Permits and Inspection Supervisor, Dr. Thomas Jemmi, Chief of Laboratories; Mr. Hans-Jorg Heiz, Chief Chemist, National Residue Monitoring Program; and Dr. Hussain Magsi, International Audit Staff Officer, FSIS. Topics of discussion included the following:

- 1. FSIS Questionnaire on the national residue program.
- 2. Swiss understanding of FSIS' delistment/relistment of establishments policy.
- 3. Salmonella and Listeria testing for ready-to-eat product.
- 4. Swiss compliance enforcement– FSIS auditor hand delivered 'FSIS Quarterly Compliance Enforcement' (9/99) report.

## Headquarters Audit

There had been no changes in the organizational structure or upper levels of inspection staffing since the last U.S. audit of Switzerland's inspection system in January 1999.

To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the inspection officials who normally conduct the periodic reviews for compliance with U.S. specifications lead the audits of the individual establishments. The FSIS auditor (hereinafter called "the auditor") observed and evaluated the process.

The auditor conducted a review of inspection system documents in conjunction with on-site audit at the establishments visited. The records review focused primarily on food safety hazards and included the following:

- Supervisory visits to establishments that were certified to export to the U.S.
- Label approval records such as generic labels.
- Sampling and laboratory analyses for residues.
- Pathogen reduction and other food safety initiatives such as SSOPs, HACCP programs generic *E. coli* testing and *Salmonella* testing.
- Control of products from livestock with conditions such as tuberculosis, cysticercosis, etc., and of inedible and condemned materials.
- Export product inspection and control including export certificates.

## **Government Oversight**

All inspection veterinarians and inspectors in establishments certified by Switzerland as eligible to export meat products to the United States were part-time BVET employees, receiving no remuneration from either industry or establishment personnel.

### **Establishment Audits**

Five establishments were certified to export meat products to the United States at the time this audit was conducted. All establishments were visited for on-site audits. At the time of audit, BVET inspection system controls and establishment system controls were in place to prevent, detect and control contamination and adulteration of products.

#### **Laboratory Audits**

During the laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to U.S. requirements. Information about the following risk areas was also collected:

- 1. Government oversight of accredited, approved, and private laboratories.
- 2. Intra-laboratory quality assurance procedures, including sample handling.
- 3. Methodology.

The Central Official Reference Laboratory in Bern was audited on February 3, 2000, and the private accredited contract UFAG, Laboratorein, AG Laboratory' in Sursee was visited on January 28, 2000. Effective controls were in place for sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, check samples program, and corrective actions. The methods used for the analyses were acceptable. No compositing of samples was done.

Switzerland's microbiological testing for *Salmonella* was being performed in a Central Official Reference Laboratory in Bern. This is the BVET's official chemical and microbiological testing laboratory in Bern. In addition, there are several Canton (State) official, and privately owned laboratories in Switzerland. These are accredited by the international and national organizations for testing various compounds and drugs. Of these, the auditor in collaboration with Dr. Jammy, Mr. Heiz and Dr. Holznagel visited the official laboratory in Bern and a private laboratory UFAG, Laboratorein, AG (UFAG) in Sursee. The U.S. required technical adequacy and capability for testing drugs, residue compounds/elements, and microorganisms were evaluated. No deviations or deficiencies were noted.

UFAG is contracted by BVET for testing chlorinated hydrocarbons, lead, cadmium, and organophosphates. The laboratory also tests generic *E. coli* carcass samples for establishment 121. In addition, a private accredited laboratory located in Belp is also contracted by BVET for

testing other residue compounds: hormones, sulfonamides, chloramphenicol, antibiotics, pharmaceutical drugs, etc. Water potability and microbiological testing for ready-to-eat product is done by State or private accredited laboratories under the control of State Public Health authorities.

All laboratories in Switzerland are accredited by a Swiss official accreditation organization called Switzerland Accreditation Service (SAS). The accreditation system was promulgated under a Swiss ordinance in 1991, and revised in 1996 for testing electromagnetic tolerance, telecom technology, chemistry, clinical chemistry, microbiology (clinical and food stuffs), civil engineering materials, mechanical testing, software testing, QM systems, and eco-management systems. The SAS is managed by Swiss Federal Office of Metrology (FMET), and is administered by a group of nine highly qualified and skilled professionals. The Series EN 45000 standards serve as a basis for their work with corresponding ISO guidelines. The SAS is accepted by European Cooperative Accreditation (EA) multilateral agreement on mutual recognition of accredited bodies.

# Establishment Operations by Establishment Number

The following operations were being conducted in the five U.S.-certified establishments visited: Swine and cattle slaughter, and cut up (Est. 121)
Cure-dried beef, and ham (Est. 201, 205, 215)
Cure-dried ham (Est. 293)

### SANITATION CONTROLS

Based on the on-site audits of establishments, the Swiss inspection system had sanitation controls in place for basic establishment facilities for condition of facilities, equipment, and product protection and handling including personal dress and hygiene practices, cross contamination, and disease control. The deviation in the areas of compliance/economic fraud control are described in the following text.

## Sanitation Standard Operating Procedures (SSOPs)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

The SSOPs were found to meet the basic FSIS regulatory requirements.

#### **Cross-Contamination**

Facilities for hand washing and/or equipment sanitizing were found to be adequate in all establishments.

### **Product Handling and Storage**

Meat products were found to be stored under sanitary conditions in all establishments.

# Personnel Hygiene and Practices

In all establishment, all employees were observed to wash their hands after contaminating them, or before continuing to work with exposed product.

### **ANIMAL DISEASE CONTROLS**

With the exceptions listed below, Switzerland's inspection system had controls in place to ensure adequate animal identification, ante-mortem and post-mortem inspection procedures and dispositions, condemned and restricted product control, and procedures for sanitary handling of returned and rework product.

It was stated that there had been no outbreaks of animal diseases of public-health significance reported since the previous U.S. audit

In establishment 121, dead on arrival (DOA) carcasses, condemned materials, and contaminated products fallen on floors are not denatured/decharacterized before shipping off-premises. However, these materials are shipped in tight containers and incinerated in a rendering facility under State Veterinary Inspection Service control. Brains, spinal cords, eyes and tonsils from animals suspected of carrying notifiable diseases, including the BSE-suspect animals, are denatured with a dye at the slaughterhouse, kept under inspection control, and incinerated in a specified rendering facility. Inedible or inedible material in other establishments (Est. 201, 205, 215, and 293) are also not denatured or decharacterized before removal from the establishment premises.

#### Residue Controls

1. National Residue Monitoring Program and Compliance Enforcement.

The auditor, at the request of IPD, evaluated and analyzed the results of the 1996 to 1998 Swiss national residues monitoring and compliance program. Thirty-seven samples were above tolerance level, and ten exceeded action level requiring enforcement action. No records on follow up investigations or enforcement action were available. The field investigations and control is under the jurisdiction of the States. Therefore, BVET leaves the enforcement action entirely to the discretion of the State officials. No feed back is available at headquarters as to the outcome of the investigation or actions taken by the state officials.

The Swiss national residue plan essentially encompasses European Union (EU) and U.S. requirements. The Swiss CY-2000 monitoring plan for slaughter-animals include testing for compounds or substances required by FSIS.

The imported meat and poultry products are tested in the official national residue and microbiological-testing laboratories in Bern.

The national plan targeted compounds are tested in officially contracted private accredited laboratories in Sursee and Belp. The official inspectors collect the samples. The plan includes sampling from calves, steers and heifers, cattle, swine and sheep. Domestic poultry products are monitored only for coccidiostats by the state laboratories under the public health inspection program.

Based on 1996-1998 testing results with low detection values for arsenic (0.1 to 0.270 ppm), and for mercury (0.03 to 0.13 ppm), BVET has requested FSIS exemption from testing these elements. The data, it was learned, had been submitted to International Policy Division (IPD), Food Safety and Inspection Service (FSIS) for consideration. Currently these elements are not being tested.

#### 2. Sulfonamide Violation

A lot of 979 pounds of 'Deboned and Smoked Prosciutto' pork (cure-dried hams) was tested positive (0.13 PPM) at U.S. port of entry in January 2000. It exceeded U.S. limit of 0.1 PPM for fresh meat. BVET's investigation indicated that the animals received from 12 holdings located in five States, were slaughtered in establishment 201 on May 27 and July 28, 1999. Over 200 hams were processed in establishment 293 for over six months (air-dried) before export to the United States.

Swiss officials stated that a similar incident of sulfa violation (cure-dried hams) at 0.11-ppm had occurred in July 1998 (refer to Swiss communications of July 22). BVET tested 10-samples from the same rejected lot with 0.05 PPM sulfamezathine concentration (refer to Swiss letter dated November 13, 1998). A conference call on the subject was held on August 26, 1998, among FSIS officials Stratmoen, Holland, and Lee, and BVET officials Dr. Dollinger, Schluep, and Hoznagel. According to BVET, FSIS in principle agreed to their argument of concentration following dehydration, and non-homogeny of one tested ham. However, the product was destroyed by FSIS.

Swiss officials maintain that salting and air-drying process of fresh meat over six months results in more than 30% moisture loss, and could result in excessive concentration of legal limit of 0.1 PPM for sulfas. They believe testing ready-to-eat finished product has no legal or scientific base, and is technically invalid. They suggest resolution of this issue as soon as possible since such incidences could continue to occur due to the nature of the process for the dehydrated product.

In Switzerland, all imported meats, in addition to other compounds, are routinely tested for sulpha residues. Establishment 121 (only U.S.-certified slaughterhouse) is subjected to the

normal National Residue monitoring program. In the future, in Establishment 121, the monitoring sampling would be re-enforced with surveillance sampling (as needed). Also when routine monitoring of finished product is found in violation ranges (over 0.1 PPM), Dr. Holznagel stated that follow up samples would be collected in establishment 201 (raw meat supplier of export Establishment 293) to determine the actual or potential violations by the livestock suppliers.

The national and private accredited laboratories report residue-monitoring results directly (only) to BVET. In case of a residue violation, BVET informs the inspector in-charge of the establishments, and the Canton (State) officials. It was stated that the federal system requires control of such products to keep them out of the human food chain. However, the enforcement procedures are not well defined or explicitly stated in the federal or state laws and no memoranda of understanding exist. The issue of documentation and enforcement procedure for residue control was discussed. BVET officials, in principle, agreed with the vagueness of the process, but no concrete comments were made available.

## SLAUGHTER/PROCESSING CONTROLS

The Swiss inspection system had adequate controls in place to ensure export product safety. Due to low demand the cattle were not being slaughtered on the day of audit. However, the beef is not eligible for use in U.S.-destined products due to BSE. Beef is imported from Argentina.

The boneless meat inspection program is being conducted in slaughter establishment 121. Other establishments which receive boneless meat for further processing are not required to have a boneless meat reinspection program. However, it was observed these establishment had voluntary quality assurance programs in place.

All establishments demonstrated an adequate control in place to prevent meat products intended for Swiss domestic consumption from being commingled with products eligible for export to the U.S.

The DOA's, condemned and inedible products are not denatured or decharacterized before off-premises shipment. According to Swiss Federal regulations §SR 817.190, SR 916.40, and SR 916.441.22, (a) the rendering establishments are required to maintain documentation of the quantity and the origin of raw material received and processed (heat treated): (b) shipping establishments are responsible to separate offals under inspection supervision; (c) dropped/floor contaminated/adulterated product, DOAs, and parts and organs of BSE and other notifiable disease suspect animal are to be sent to an exclusive rendering facility (only one in Switzerland) for incineration; and not to be sent to meat-and-bone meal and fat rendering establishments, and (d) all containers shall be tight, lockable, and easy to clean, and transported in identified containers.

# **HACCP Implementation**

All establishments approved to export meat products to the U.S. are required to have developed and implemented a Hazard Analysis Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment B).

The following system deficiencies were noted at the time of audit.

- In establishments 121, 205, 215, and 293, pre-shipment review was not done.
- In establishments 205 and 215, documentation on corrective action was incomplete.
- In establishments 215 and 293, CCPs were not identified, however critical limits (CL) for each process were defined and identified.
- In establishments 121, 201 and 215, failure to analyze and/or identify all possible hazards likely to occur.
- Documentation in all establishments was inadequate for respective deficiencies cited above.

Official verification of HACCP plans in all establishments was incomplete, and/or the plans were being processed. BVET officials stated that continuing education, technical reconciliation seminars, and discussion were in progress with the industry. The next seminar and workshop had been scheduled in March 2000. Swiss authorities assured that all deviations noted during the audit would be the central theme of the meetings. They had assurance of industry to reconcile all variances noted according to U.S. requirements.

#### Testing for Generic E. coli

Switzerland has adopted the FSIS regulatory requirements for *E. coli* testing.

One (Est. 121) of the establishments slaughters cattle, swine and sheep. The predominant species slaughtered is swine. The basic FSIS regulatory requirements for generic *E. coli* testing were audited and evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment C).

The *E. coli* testing programs were found to meet the basic FSIS regulatory requirements. The exception from U.S. testing programs is that the private laboratory sends the results directly to BVET headquarters in Bern, the results are reviewed and transmitted to the establishment for process control compliance.

Additionally, establishments had adequate controls in place to prevent meat products intended for Switzerland's domestic consumption from being commingled with products eligible for export to the U.S.

#### ENFORCEMENT CONTROLS

Except as noted under appropriate items discussed in the text, at the time of audit, no deficiencies were found for: ante-and post-mortem inspection procedures and dispositions, boneless meat reinspection, shipment security, including shipment between establishments, prevention of commingling of product intended for export to the United States with domestic product, inspection supervision and documentation, the importation of only eligible livestock or poultry from other countries from other countries for further processing were in place and effective in ensuring that products produced by the establishment were wholesome, unadulterated, and properly labeled. In addition, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

#### Testing for Salmonella Species

One of the establishments (Est. 121) audited was required to meet the basic FSIS regulatory requirements for *Salmonella* testing, and was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment D). Testing was not done in processed product establishments. These establishments do not prepare ground meat.

# Testing Ready-to eat Product for Listeria monocytogenes and Salmonella Species.

Ready-to-eat products are routinely sampled by the establishments and tested by accredited private laboratories. Swiss official standards (action level) for imported and exported product are as follows:

- a. *Listeria monocytogenes* shall not be detected in 25g of product through qualitative analytical method using enrichment of microorganism's analytical procedure, and it shall not exceed 100cfu/g in cure-dried beef and ham (with water activity of < 0.92) when determined by a quantitative method, with detectable level of 100cfu/g.
- b. *Salmonella* spp. shall not be detectable in 25g of product through qualitative method using enrichment of microorganism's analytical procedure.

Establishments are responsible to ensure that the products meet these standards. When results exceed action level (not detectable in 25g of product), the establishments are required to take appropriate action to prevent distribution of such products in the market. The appropriate actions include collecting additional samples from the lot in question and other available lots from product contact surfaces, for laboratory re-evaluation in the official laboratory. The official inspectors routinely verify these actions, and enforce the requirements.

BVET's microbiological testing experience with cure-dried products, it was stated, indicates that the maturation process (cure-drying) inhibits the growth of *Listeria* and *Salmonella* at water activity of < 0.92 and < 0.95 respectively, and renders *Enterobacteriaceae* microorganisms virtually harmless.

#### **Species Verification Testing**

At the time of this audit, Switzerland was not exempt from the species verification testing requirement. The auditor verified that species verification testing was being conducted in accordance with FSIS requirements.

#### Monthly Reviews

These reviews were being performed by the regional supervisors appointed by the respective States. The internal review program was applied equally to both export and non-export establishments. Internal review visits were not announced in advance, and were conducted, at times by individuals, at least once monthly. The records of audited establishments were kept in the inspection offices of the individual establishments, and copies were also kept in the State headquarters, and were routinely maintained on file for a minimum of two years. In the event that an establishment is found, during one of these internal reviews, to be out of compliance with U.S. requirements, the regional supervisor or inspector-in-charge may recommend delistment in their reports to headquarters. The FVO may then withdraw the approval to export from the establishment if the deficiencies warrant such an action. Before it may again qualify for eligibility to be reinstated, the Chief of State Inspection system conducts an in-depth review, formulates a plan for corrective action and preventive measures, and reports results to BVET in Bern for evaluation and with recommendations for reinstatement of export eligibility.

After observing the internal reviewers' activities in the field, the auditor was confident in their professionalism, thoroughness, and knowledge of U.S. requirements, and in the effectiveness of Switzerland's internal review program as a whole.

#### **Enforcement Activities**

No change in the BVET policy or regulations was reported since FSIS December 1998 audit.

Inspection system controls were in place to ensure adequate export product identification, inspector verification, and export certificates. A single standard of control throughout the establishments for products entering the establishments from outside sources was also in place. The export product security is ensured by application of official transit devices.

# Exit Meeting

An exit meeting was conducted in Bern on February 7. The Swiss participants were Dr. Jakob Schluep (chaired the meeting in the absence of Dr. Dollinger on travel status abroad), Drs. Silke Holznagel, Thomas Jemmi, and Chris Jaggi. The following topics were discussed:

• Lack of or failure to analyze and/or identify hazards likely to occurs in establishments 121, 201, and 215; failure to identify critical control points in establishments 215 and 293; failure to document corrective actions taken in establishments 205 and 215, and failure to conduct pre-shipment review in establishments 121, 205, 215, and 293.

- Dead on arrival (DOA) carcasses, and condemned/inedible product and material not being denatured or decharacterized before removal from establishment premises.
- Sulpha violation of ready-to-eat products imported in to the United States.

BVET officials stated that continuing education, technical reconciliation seminars, and discussion were in progress with the industry. The next seminar and workshop had been scheduled in March 2000. Swiss authorities assured that all deviations noted during the audit would be the central theme of the meetings. They had assurance of industry to reconcile all variances noted according to U.S. requirements. Dr. Holznagel stated that a conference with the U.S.-certified establishments had already been planned to discuss outcome of the recent FSIS audit, and to clarify the HACCP implementation requirements with the industry officials and the inspectors.

It was also stated that Swiss State Inspection systems had legal authority and adequate controls in place to control DOA's, and condemned/inedible products.

Dr. Thomas Jemmi stated that Swiss argument for U.S.-acceptance of Swiss ready-to-eat curdried beef or hams is scientific, and stated that all imported and domestic fresh meats are routinely monitored for sulpha drugs and U.S. requirements are enforced.

#### **CONCLUSION**

The inspection system of Switzerland was found to have effective controls to ensure that product destined for export to the United States was produced under conditions equivalent to those which FSIS requires in domestic establishments. All of the five U.S.-certified establishments were acceptable at the time of audit. However, the procedures for residue control enforcement are not documented or clearly defined on jurisdiction and control; the DOA's, condemned and inedible products are not denatured or decharacterized before off-premises shipment; and the HACCP verification and implementation oversight by the inspection service needs to re-emphasize.

(signed) *Dr. Hussain Magsi*Dr. Hussain Magsi, DVM, MS
International Audit Staff Officer

# **Attachments**

- A. Data collection instrument for SSOPs
- B. Data collection instrument for HACCP programs
- C. Data collection instrument for *E. coli* testing.
- D. Data collection instrument for Salmonella testing
- E. Laboratory audit form
- F. Individual Foreign Establishment Audit Forms
- G. Written Foreign Country's Response to the Draft Final Audit Report
- H. FSIS Response(s) to Foreign Country Comments

#### **Data Collection Instrument for SSOPs**

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

- 1. The establishment has a written SSOP program.
- 2. The procedure addresses pre-operational sanitation.
- 3. The procedure addresses operational sanitation.
- 4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
- 5. The procedure indicates the frequency of the tasks.
- 6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
- 7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
- 8. The procedure is dated and signed by the person with overall on-site authority.

| Est. # | 1.Written<br>program<br>addressed | 2. Pre-op<br>sanitation<br>addressed | 3. Oper.<br>sanitation<br>addressed | 4. Contact<br>surfaces<br>addressed | 5. Frequency addressed | 6. Responsible indiv. identified | 7. Documentation done daily | 8. Dated and signed |
|--------|-----------------------------------|--------------------------------------|-------------------------------------|-------------------------------------|------------------------|----------------------------------|-----------------------------|---------------------|
| 121    | V                                 | V                                    | $\sqrt{}$                           | <b>V</b>                            | $\sqrt{}$              | $\sqrt{}$                        | $\sqrt{}$                   | $\sqrt{}$           |
| 201    | V                                 | V                                    | $\sqrt{}$                           | <b>V</b>                            | $\sqrt{}$              | $\sqrt{}$                        | $\sqrt{}$                   | $\sqrt{}$           |
| 205    | V                                 | V                                    | $\sqrt{}$                           | <b>V</b>                            | $\sqrt{}$              | $\sqrt{}$                        | $\sqrt{}$                   | $\sqrt{}$           |
| 215    | V                                 | V                                    | V                                   | V                                   | V                      | V                                | V                           | V                   |
| 293    | V                                 | V                                    | V                                   | V                                   | V                      | V                                | V                           | V                   |

# **Data Collection Instrument for HACCP Programs**

Each of the establishments approved to export meat products to the U.S. was required to have developed and implemented a Hazard Analysis Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

- 1. The establishment has a flow chart that describes the process steps and product flow.
- 2. The establishment had conducted a hazard analysis.
- 3. The analysis includes food safety hazards likely to occur.
- 4. The analysis includes the intended use of or the consumers of the finished product(s).
- 5. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
- 6. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
- 7. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
- 8. The plan describes corrective actions taken when a critical limit is exceeded.
- 9. The HACCP plan was validated using multiple monitoring results.
- 10. The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.
- 11. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
- 12. The HACCP plan is dated and signed by a responsible establishment official.

| Est.#   | 1. Flow<br>diagram | 2. Haz-<br>ard an- | *3. All<br>hazards | 4. Use<br>& users | 5. Plan<br>for each | *6.<br>CCPs | 7. Mon-<br>itoring | 8. Corr.<br>actions | 9. Plan<br>valida- | 10.Ade-<br>quate | 11.Ade-<br>quate | 12. Dat-<br>ed and |
|---------|--------------------|--------------------|--------------------|-------------------|---------------------|-------------|--------------------|---------------------|--------------------|------------------|------------------|--------------------|
| Lat. II | diagram            | alysis             | ident-             | include-          | hazard              | for all     | is spec-           | are des-            | ted                | verific.         | docu-            | signed             |
|         |                    | conduct            | ified              | ed                |                     | hazards     | ified              | cribed              |                    | Proced-          | menta-           |                    |
|         |                    | -ed                |                    |                   |                     |             |                    |                     |                    | ures             | tion             |                    |
| 121     | ✓                  | ✓ No               | No                 | ✓                 | ✓                   | ✓           | ✓                  | ✓                   | ✓                  | *No              | **               | ✓                  |
| 201     | ✓                  | <b>√</b> No        | No                 | ✓                 | ✓                   | ✓           | ✓                  | ✓                   | ✓                  | *No              | **               | <b>✓</b>           |
| 205     | ✓                  | ✓                  | ✓                  | ✓                 | ✓                   | ✓           | ✓                  | No                  | ✓                  | *No              | **               | ✓                  |
| 215     | ✓                  | <b>√</b> No        | No                 | ✓                 | ✓                   | No          | ✓                  | No                  | ✓                  | *No              | **               | ✓                  |
| 293     | ✓                  | <b>√</b>           | <b>√</b>           | <b>√</b>          | <b>√</b>            | No          | <b>√</b>           | ✓                   | ✓                  | *No              | **               | <b>√</b>           |

<sup>\*</sup> Official verification of the plans was incomplete, and/or plans were being re-assessed.

<sup>\*\*</sup> Documentation was inadequate in all establishments for respective deficiencies noted in the table.

# Data Collection Instrument for Generic E. coli Testing

Establishment 121 (only U.S.-certified slaughter) was evaluated to determine if the basic FSIS regulatory requirements for generic *E. coli* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

- 1. The establishment has a written procedure for testing for generic E. coli.
- 2. The procedure designates the employee(s) responsible to collect the samples.
- 3. The procedure designates the establishment location for sample collecting.
- 4. The sample collection is done on the predominant species being slaughtered.
- 5. The sampling is done at the frequency specified in the procedure.
- 6. The proper carcass site(s) and/or collection methodology (sponge or excision) is being used for sampling.
- 7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
- 8. The laboratory is analyzing the sample using an AOAC Official Method or an equivalent method.
- 9. The results of the tests are being recorded on a process control chart showing the most recent test results.
- 10. The test results are being maintained for at least 12 months.

|        | 1.Writ-  | 2. Samp- | 3.Samp-   | 4. Pre-   | 5. Samp-  | 6. Pro-  | 7. Samp-  | 8. Using | 9. Chart  | 10. Re-    |
|--------|----------|----------|-----------|-----------|-----------|----------|-----------|----------|-----------|------------|
| Est. # | ten pro- | ler des- | ling lo-  | domin.    | ling at   | per site | ling is   | AOAC     | or graph  | sults are  |
|        | cedure   | ignated  | cation    | species   | the req'd | or       | random    | method   | of        | kept at    |
|        |          |          | given     | sampled   | freq.     | method   |           |          | results   | least 1 yr |
| 121    |          | √        | $\sqrt{}$ | $\sqrt{}$ |           |          | $\sqrt{}$ |          | $\sqrt{}$ | $\sqrt{}$  |

# Data Collection Instrument for Salmonella testing

Each slaughter establishment was evaluated to determine if the basic FSIS regulatory requirements for *Salmonella* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

- 1. Salmonella testing is being done in this establishment.
- 2. Carcasses are being sampled.
- 3. Ground product is being sampled.
- 4. The samples are being taken randomly.
- 5. The proper carcass site(s) and/or collection of proper product (carcass or ground) are being used for sampling.
- 6. Establishments in violation are not being allowed to continue operations.

|        | 1. Testing  | 2. Carcasses | 3. Ground  | 4. Samples | 5. Proper site | 6. Violative |
|--------|-------------|--------------|------------|------------|----------------|--------------|
| Est. # | as required | are sampled  | product is | are taken  | and/or         | est's stop   |
|        |             |              | sampled    | randomly   | proper prod.   | operations   |
| 121    | V           | V            | N.A.       | V          | V              | V            |